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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/028,075	12/21/2001	Nisar Asmed Khan	2183-5223US	1102

24247 7590 05/25/2005

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EXAMINER	
MCKELVEY, TERRY ALAN	
ART UNIT	**PAPER NUMBER**
1636	

DATE MAILED: 05/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/028,075	KHAN ET AL.	
	Examiner	Art Unit	
	Terry A. McKelvey	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 February 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) *6-22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/22/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

5-0-0

DETAILED ACTION

All objections and rejections not repeated in the instant Action have been withdrawn due to applicant's response to the previous Action.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restrictions

Claims 6-22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 10/28/03.

Claim Rejections - 35 USC § 102

Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Lunardi-Iskandar et al (U.S. Patent No. 5,677,275). This rejection is maintained for reasons of record set forth in the paper mailed 12/15/05. Applicants' arguments filed 2/22/05 have been fully considered but they are not deemed to be persuasive.

Lunardi-Iskandar et al teach contacting cells in animals (mice) with hCG by injecting the mice with hCG (Example 6). This reads on contacting an oligopeptide of at most 30 amino acids long or a peptide derivative thereof with at least one cell because the instant specification defines a derivative of a peptide as an amino acid sequence which has been altered such that the functional properties of the sequence are essentially the same in kind, not necessarily in amount, and hCG reads on peptide derivative of a biologically active fragment of hCG or beta-subunit of hCG which is not more than 30 amino acids long such as the 109-119 aa beta-hCG oligopeptide (e.g., claim 7 of Lunardi-Iskandar et al). The reference teaches that the polypeptide gene product of c-rel was detected in the cells from the mice treated with hCG and not in the cells of mice that had not been treated with hCG (column 13, lines 10-17), which determines the ratio.

Response to Arguments

The applicant argues that Lunardi-Iskandar et al do not disclose each and every element of any of claims 1-5, specifically, the reference does not disclose contacting an oligopeptide of at most 30 amino acids long or a peptide derivative thereof with at least one cell to regulate expression

of a gene as recited in claim 1. As part of the argument the applicant argues that the oligopeptide and the peptide derivative thereof are not more than 30 amino acids long (in the claimed invention). This argument is not persuasive for the following reasons. Claim 1 recites "... an oligopeptide of at most 30 amino acids long or a peptide derivative thereof ...". It is only the oligopeptide that is limited to at most 30 amino acids long. The "peptide derivative thereof" recited in the claim can only refer to the oligopeptide, and thus is actually interpreted to mean "peptide derivative of the oligopeptide (which oligopeptide is at most 30 amino acids long)". There is absolutely no limitation that the peptide derivative itself is at most 30 amino acids long, despite applicant's assertion to the contrary. The instant specification defines a derivative of a peptide as an amino acid sequence which has been altered such that the functional properties of the sequence are essentially the same in kind, not necessarily in amount. Thus, a peptide derivative of an oligopeptide can be larger than the polypeptide if the derivation is by attachment of a larger sequence via a peptide bond and the resulting polypeptide has essentially the same functional properties. In the instant case, as described in the rejection above, the 109-119 aa beta-hCG oligopeptide taught by Lunardi-Iskandar et al is an oligopeptide of at most

30 amino acids. The polypeptide **hCG itself** or **beta hCG itself** reads on peptide derivative of a biologically active fragment of hCG or beta-subunit of hCG which is not more than 30 amino acids long because hCG or beta hCG can be seen as an alteration of the 109-119 aa beta-hCG oligopeptide by the attachment of additional amino acids, but hCG and beta hCG polypeptides have functional properties that are essentially the same in kind, not necessarily amount as compared to the 109-119 aa beta-hCG oligopeptide. Therefore, the method taught by the cited reference does read on the invention as claimed.

The applicant argues that Lunardi-Iskandar et al do not disclose placing beta-hCG (109-119) in contact with at least one cell and determining the presence of a NF-kappaB/Rel protein as claimed. This argument is not persuasive in overcoming the instant rejection because the instant rejection is not based upon an argument that beta-hCG (109-119) was taught as being assayed as claimed. The rejection was based upon a peptide derivative of beta-hCG (109-119), hCG itself or beta-hCG was taught in the context of the claimed invention, as clearly described above.

With regard to claim 5, the applicant argues that Lunardi-Iskandar et al do not disclose detecting any ratio since the word "ratio" does not appear in the cited passage. This

argument is not persuasive because claim 5 is drawn to "determining the ratio of said NF-kappaB/Rel protein found in step b) to gene product found in step c)." Underlining added for instant emphasis. In this context, "determining the ratio" is merely a mental step that holds no patentable weight because it may be arrived at totally within the mind, without any requirement in the claim that the ratio is reported or displayed in any way. Arriving at the data for determining the ratio is taught by the reference as indicated in the rejection above: The reference teaches that the polypeptide gene product of c-rel was detected in the cells from the mice treated with hCG and not in the cells of mice that had not been treated with hCG (column 13, lines 10-17). What mental steps that the person practicing the method in the reference takes with the data is not relevant to what the reference teaches with regard to anticipation of the claimed invention (hence it is not relevant that the reference fails to teach "determining the ratio") because patentability of a method is determined by the physical steps of the claimed method, not any mental steps. In another way of looking at this issue, how is one to distinguish between two methods that are taught as comprising identical physical method steps on the basis of what the person teaching or practicing the method is thinking? The methods are physically carried out identically.

Putting in some mental step limitation results in no change whatsoever in the claimed method. There is no physical distinction between methods based upon thought or mental steps and thus, the claimed method drawn to determining a ratio, which can be done mentally, is indistinguishable from the same method which does not explicitly teach the mental step because what is actually physically carried out is identical whether the mental step is explicitly present or not. Therefore, the actual, physical limitations of the claimed invention are taught by the cited reference and thus the claimed invention is anticipated by the teachings of Lunardi-Iskandar et al.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is 571-273-8300. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily

from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Any inquiry concerning rejections or objections in this communication or earlier communications from the examiner should be directed to Terry A. McKelvey whose telephone number is (571) 272-0775. The examiner can normally be reached on Monday through Friday, except for Wednesdays, from about 7:30 AM to about 6:00 PM. A phone message left at this number will be

responded to as soon as possible (i.e., shortly after the examiner returns to his office).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel can be reached at (571) 272-0781.

Terry A. McKelvey, Ph.D.
Primary Examiner
Art Unit 1636

May 22, 2005